CLAIMS

What is claimed is:

1. An apparatus for minimally invasive therapy modification of tissue to be treated, comprising:

an elongated shaft having at least one lumen extending therethrough; and

inflatable means coupled to an end of said shaft for separating and isolating tissue to be treated from adjacent tissue.

2. An apparatus as recited in claim 1, wherein said inflatable means comprises a balloon.

3. An apparatus as recited in claim 1, further comprising a temperature sensor coupled to said inflatable means and configured to sense temperature of said treated tissue and said adjacent tissue.

4. An apparatus as recited in claim 1, further comprising a radiation sensor coupled to said inflatable means and configured to sense exposure of said treated tissue and said adjacent tissue to radiation.

5. An apparatus as recited in claim 1, further comprising means for inflating said inflatable means.

6. An apparatus as recited in claim 5, wherein said means for inflating comprises:

a fluid disposed within at least one of said lumens of said shaft; and

means for moving said fluid through said lumen to said inflatable means, wherein said inflatable means is inflated.

7. An apparatus as recited in claim 6, wherein said means for moving said fluid comprises a syringe and a valve.

8. An apparatus as recited in claim 6, wherein said fluid comprises a liquid, or a gas or a mixture of a liquid and a gas.

9. An apparatus as recited in claim 6, wherein said means for moving fluid further comprises means for cycling said fluid through said lumens of said shaft and said inflation means.

10. An apparatus for minimally invasive therapy modification of tissue to be treated, comprising:

an elongated shaft having at least one lumen extending therethrough; and

an inflatable member coupled to an end of said shaft;

said inflatable member configured to separate and isolate tissue to be treated from adjacent tissue.

11. An apparatus as recited in claim 10, wherein said inflatable member comprises a balloon.

12. An apparatus as recited in claim 10, further comprising a temperature sensor coupled to said inflatable member and configured to sense temperature of said treated tissue and said adjacent tissue.

13. An apparatus as recited in claim 10, further comprising a radiation sensor coupled to said inflatable member and configured to sense exposure of said treated tissue and said adjacent tissue to radiation.

14. An apparatus as recited in claim 10, further comprising means for inflating said inflatable member.

15. An apparatus as recited in claim 14, wherein said means for inflating comprises:

a fluid disposed within at least one of said lumens of said shaft; and

means for moving said fluid through said lumen to said inflatable member, wherein said inflatable member is inflated.

16. An apparatus as recited in claim 15, wherein said means for moving said fluid comprises a syringe and a valve.

17. An apparatus as recited in claim 15, wherein said fluid comprises a liquid, or a gas or a mixture of a liquid and a gas.

18. An apparatus as recited in claim 15, wherein said means for moving fluid further comprises means for cycling said fluid through said lumens of said shaft and said inflatable member.

19. An apparatus as recited in claim 10, wherein said inflatable member further comprises multiple compartments, each compartment capable of inflating independently of the other compartments.

20. An apparatus for minimally invasive therapy modification of tissue to be treated, comprising:

an elongate tubular shaft having a proximal end, a distal end and one or more lumens extending therethrough;

said distal end of said shaft having a tip, said tip and said shaft configured for introduction into the body of a patient;

an inflatable member having an interior and an exterior disposed on said distal end of said elongate tubular shaft;

said interior of said inflatable member being open to at least one of said lumens of said shaft; and

means for inflating said inflatable member;

wherein said inflatable member is configured to separate and isolate tissue to be treated from adjacent tissue.

21. An apparatus as recited in claim 20, further comprising a sensor connected to said distal end of said shaft.

22. An apparatus as recited in claim 20, further comprising a sensor connected to said inflatable member.

23. An apparatus as recited in claim 21, wherein said sensor is selected from the group of sensors consisting essentially of a thermocouple, a fiber optic sensor, a thermistor, and a radiation dosimeter.

24. An apparatus as recited in claim 22, wherein said sensor is selected from the group of sensors consisting essentially of a thermocouple, a fiber optic sensor, a thermistor, and a radiation dosimeter.

25. An apparatus as recited in claim 20, wherein said inflatable member comprises a plurality of balloons connected to said distal end of said shaft and configured for substantially simultaneous inflation or deflation.

26. An apparatus as recited in claim 20:

wherein said inflatable member comprises a plurality of balloons connected to said distal end of said shaft;

wherein each of said balloons is in fluid communication with at least one of said lumens; and

wherein each of said balloons can be selectively inflated or deflated.

27. An apparatus as recited in claim 20, further comprising:

a fluid disposed in said lumen of said shaft;

wherein fluid flow into said lumen causes said inflatable member to inflate.

28. An apparatus as recited in claim 27, wherein said fluid comprises at least one of a gas or liquid.

29. An apparatus as recited in claim 27, wherein said fluid comprises a mixture of a gas and a liquid.

30. An apparatus as recited in claim 27, wherein said fluid is selected from the group of fluids consisting essentially of air, water, oil, perfluorocarbons, diagnostic imaging contrast agents, and saline solution.

31. An apparatus as recited in claim 20, wherein said elongate shaft is formed from a material selected from the group consisting essentially of stainless steel hypodermic tubing, polyimide, polyethylene, polystyrene, polycarbonate, extrudable polymer, thermoplastic, silicone, rubber, composite, brass, titanium, aluminum, and ceramic.

32. An apparatus according to claim 20, wherein said tip of said shaft is pointed to allow direct insertion of the tip and shaft into body tissue.

33. An apparatus as recited in claim 20:

wherein said elongate shaft is dimensioned to be coupled with a catheter placement device having a slightly larger diameter than said shaft;

wherein said catheter placement device is placed over the tip and distal end of said shaft and inflatable member during insertion and placement; and

wherein said catheter placement device is configured to decouple from said shaft after insertion and placement of the shaft into the body.

34. An apparatus as recited in claim 20:

wherein said elongate shaft and said inflatable member is placed within a catheter placement device having a slightly larger diameter than said shaft and is placed over the distal portion;

wherein said catheter placement device is placed over the tip and distal end of said shaft and inflatable member during insertion and placement; and

wherein said catheter placement device is configured to slide back on said

shaft after insertion and placement of the shaft into the body.

35. An apparatus as recited in claim 20, wherein said inflatable member is made of an elastic material that is configured to expand during inflation.

36. An apparatus as recited in claim 20, wherein said inflatable member is made of an inelastic material that is configured to inflate to a predetermined volume and shape.

37. An apparatus as recited in claim 35, wherein said inflatable member is made of an elastic material that is configured to take the shape of a target tissue, a tissue space or an organ.

38. An apparatus as recited in claim 36, wherein said inflatable member is made of an inelastic material that is configured to take the shape of a target tissue, a tissue space or an organ.

39. An apparatus as recited in claim 20, wherein said inflatable member is made of a porous material that is configured to allow the transfer of fluid from the interior of said inflatable member to the exterior of said inflatable member.

40. An apparatus as recited in claim 20, wherein said inflatable member has a metallized surface that is capable of conducting an electric current.

41. An apparatus as recited in claim 20, wherein said inflatable member is optically transparent.

42. An apparatus as recited in claim 20, wherein said inflatable member is optically opaque.

43. An apparatus as recited in claim 20, wherein said inflatable member has a generally spherical shape when fully inflated.

44. An apparatus as recited in claim 20, wherein said inflatable member has a generally ovoid shape when fully inflated.

45. An apparatus as recited in claim 20, wherein said inflatable member has a generally spoon shape when fully inflated.

46. An apparatus as recited in claim 20, wherein said inflatable member has a generally elliptical shape when fully inflated.

47. An apparatus as recited in claim 20, wherein said inflatable member has a generally cylindrical shape when fully inflated.

48. An apparatus as recited in claim 20:

wherein said inflatable member includes a plurality of chambers;

said chambers in fluid communication with at least one other chamber.

49. An apparatus as recited in claim 20, wherein said inflatable member further comprises:

a plurality of partitions compartmentalizing the interior of said inflatable member;

each compartment configured to inflate independently of the other compartments.

50. An apparatus as recited in claim 20, wherein said inflatable member is made from a material selected from the group consisting essentially of silastic, silicone, c-flex, polyester, Mylar, polyurethane, polyethylene, polyvinyl, latex, and rubber.

51. An apparatus for minimally invasive isolation of tissue to be treated, comprising:

an elongate tubular shaft having a proximal end and a distal end;

said shaft having a first fluid passage and a second fluid passage;

said shaft having a plurality of lumens extending therethrough;

said distal end of said shaft having a closed tip said tip and distal end configured for introduction into the body of a patient;

an inflatable member having an interior and an exterior disposed on said distal end of said elongate tubular shaft;

said interior of said inflatable member being in fluid communication with said first fluid passage and said second fluid passage of said shaft;

a fluid;

means for selectively flowing said fluid into said shaft through said first fluid passage to said interior of said inflatable member and through said second fluid passage, and inflating said inflatable member;

wherein said inflatable member is adapted to separate and isolate tissue to be treated from adjacent tissue.

52. An apparatus as recited in claim 51, further comprising means for decreasing the temperature of said fluid during fluid circulation.

53. An apparatus as recited in claim 52, further comprising means for increasing temperature of said fluid during fluid circulation.

54. An apparatus as recited in claim 51, further comprising means for regulating the pressure of said fluid.

55. An apparatus as recited in claim 51, further comprising means for regulating the flow of said fluid.

56. An apparatus as recited in claim 51, wherein said fluid comprises a gas.

57. An apparatus as recited in claim 56, wherein said gas comprises air.

58. An apparatus as recited in claim 51, wherein said fluid comprises a liquid.

59. An apparatus as recited in claim 58, wherein said liquid is selected from the group of liquids consisting essentially of water, silicon oil, diagnostic imaging contrast agents and saline solution.

60. An apparatus as recited in claim 51, wherein said inflatable member comprises a plurality of balloons connected to said distal end of said shaft and in fluid communication with said first fluid passage and said second fluid passage.

61. An apparatus as recited in claim 51, further comprising:

a plurality of sensors connected to said distal end of said shaft;

said sensors operably coupled with a measuring device outside of the body of a patient.

62. An apparatus as recited in claim 61, wherein said sensors comprise a miniature thermocouple configured to measure the temperature of the circulating fluid within said inflating member.

63. An apparatus as recited in claim 61, wherein said sensor comprises a miniature thermocouple configured to measure the temperature of the tissue surrounding the inflating member.

64. A method for treatment of the prostate gland, comprising:

inserting a catheter assembly into the general proximity of the target prostate

gland;

placing the distal end of said inserted catheter assembly in a space between the rectum and the prostate gland;

inflating an inflatable member of the catheter assembly between the prostate gland and the rectal wall;

initiating and conducting treatment of the prostate gland tissue; and

deflating the inflatable member of the catheter assembly and removing said catheter assembly once treatment is completed.

65. A method as recited in claim 64, further comprising:

sensing and monitoring the temperature of the rectal wall and the surface of prostate gland during the treatment of the prostate gland.

66. A method as recited in claim 64, further comprising:

sensing and monitoring the temperature of the surface of the inflatable member during the treatment of the prostate gland.

67. A method as recited in claim 64, further comprising:

monitoring the temperature of a fluid within said inflatable member during the treatment of the prostate gland.

68. A method as recited in claim 64, further comprising:

inflating or circulating a thermally conductive fluid through said catheter assembly during the treatment of the prostate gland by thermotherapy.

69. A method as recited in claim 64, further comprising:

regulating the temperature and flow of said thermally conductive fluid through said catheter assembly during the treatment of the prostate gland.

70. A method as recited in claim 64, further comprising:

inflating or circulating a thermally non-conductive fluid through said catheter

assembly during the treatment of the prostate gland by thermotherapy.

71. A method as recited in claim 64, further comprising:

regulating the temperature and flow of said thermally non-conductive fluid through said catheter assembly during the treatment of the prostate gland.

72. A method as recited in claim 64, further comprising:

inflating or circulating a fluid through said catheter assembly that is below the normal body temperature during the treatment of the prostate gland by thermotherapy.

73. A method as recited in claim 64, further comprising:

inflating said inflatable member with a gas to physically displace the prostate from the rectal wall and form an acoustic barrier to protect rectal wall or surrounding tissue; and

initiating and completing ultrasonic treatment of the prostate gland.

74. A method as recited in claim 64, further comprising:

inflating said inflatable member with an acoustically transmissible material to allow for diagnostic imaging;

replacing said acoustically transmissible material with an acoustically blocking material to physically displace the prostate from the rectal wall; and form an acoustic barrier to protect the rectal wall or surrounding tissue; and

initiating and completing ultrasonic treatment of the prostate gland.

75. A method as recited in claim 74, wherein pressure within said catheter assembly remains constant during the replacement of said gas with said liquid.

76. A method as recited in claim 74, wherein the temperature of said liquid replacing said gas is lower than the temperature of the body.

77. A method as recited in claim 74, wherein the temperature of said liquid replacing said gas is higher than the temperature of the body.

78. A method as recited in claim 64, wherein the insertion and placement of the catheter assembly is monitored by a process selected from the group consisting essentially of CT, fluoroscopic imaging, magnetic resonance imaging and transrectal or external ultrasonic imaging and X-ray.

79. A method for treatment of a diseased tissue site, comprising:

inserting a catheter assembly into the general proximity of a diseased tissue site;

placing the distal end of said inserted catheter assembly at an edge between the target tissue site and a sensitive healthy tissue or non-targeted site;

inflating an inflatable member of the catheter assembly between the target tissue and non-targeted tissue;

initiating and conducting treatment of the target tissue once the inflatable member is inflated; and

deflating the inflatable member of the catheter assembly and removing said catheter assembly once treatment is completed.

80. A method as recited in claim 79, further comprising:

sensing and monitoring the temperature of the sensitive tissues during the treatment of the target tissue.

81. A method as recited in claim 79, further comprising:

monitoring the temperature of the inflatable member during the treatment of the target tissue.

82. A method as recited in claim 79, further comprising:

cycling a thermally conductive fluid through said catheter assembly during the treatment of the target tissue by thermotherapy.

83. A method as recited in claim 82, further comprising:

regulating at least one of the temperature, pressure and flow of said thermally conductive fluid through said catheter assembly during the treatment of the target tissue.

84. A method as recited in claim 79, further comprising:

inflating said inflatable member with a gas to physically displace the target tissue from the sensitive tissue and form an acoustic barrier;

initiating and completing ultrasonic treatment of the target tissue; and

replacing said gas within said inflatable member and said catheter assembly with a liquid after the conclusion of the ultrasonic treatment of the target tissue.

85. A method as recited in claim 79, further comprising:

regulating the pressure of said gas within said catheter assembly and said inflatable member.

86. A method as recited in claim 84, wherein the temperature of said liquid replacing said gas is lower than the temperature of the body.

87. A method as recited in claim 79, wherein the insertion and placement of the catheter assembly is monitored by a process selected from the group consisting essentially of CT fluoroscopic imaging, magnetic resonance imaging and transrectal or external ultrasonic imaging.

88. A method for radiation treatment of the prostate gland, comprising:

inserting a catheter assembly into the general proximity of the target prostate gland;

placing the distal end of said inserted catheter assembly in a space between the rectum and the prostate gland;

inflating an inflatable member of the catheter assembly between the prostate gland and the rectal wall ;

initiating and conducting radiation treatment of the prostate gland tissue; and

deploying said inflatable member and said catheter assembly for the duration of the implantation.

89. A method as recited in claim 88, further comprising:

inflating said inflatable member with material that modifies radiation dose distribution.

90. A method as recited in claim 88, further comprising the step of:

sensing the exposure of said catheter assembly to radiation after initiating and conducting radiation therapy of said prostate gland.

91. A method as recited in claim 88, further comprising the step of:

sensing the exposure of tissues surrounding the prostate gland to radiation after initiating and conducting radiation therapy of said prostate gland.

92. A method as recited in claim 88, further comprising the step of:

repositioning tissues that are in close proximity to the prostate gland prior to initiating and conducting radiation therapy of said prostate gland.

93. A method for treatment of a diseased tissue site, comprising:

inserting a catheter assembly into the general proximity of a diseased tissue site;

placing the distal end of said inserted catheter assembly at an edge between the target tissue site and a sensitive healthy tissue or non-targeted site;

inflating a first chamber of an inflatable member of the catheter assembly between the target tissue and non-targeted tissue;

inflating a second chamber of said inflatable member of the catheter assembly between the target tissue and non-targeted tissue;

initiating and conducting treatment of the target tissue once the inflatable member is inflated; and

deflating the inflatable member of the catheter assembly and removing said catheter assembly once treatment is completed.

94. A method as recited in claim 93, further comprising:
inflating said first chamber of said inflatable member with a first fluid; and
inflating said second chamber of said inflatable member with a second fluid.

95. A method as recited in claim 93, further comprising:
cycling said first fluid through said first chamber and cycling said second fluid through said second chamber during the treatment of said target tissue.

96. A method as recited in claim 93, further comprising:
regulating the temperature of said first fluid and said second fluid.

97. A method as recited in claim 96, further comprising:
sensing the temperature of said first fluid and said second fluid.

98. A method as recited in claim 93, further comprising:
delivering therapeutic or diagnostic agents to the tissues surrounding the distal end of the catheter assembly.